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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/754,947	01/04/2001	Bruce A. Lee	14907003310	4527

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TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER
BASKAR, PADMAVATHI

ART UNIT	PAPER NUMBER
1645	16

DATE MAILED: 06/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/754,947	LEE ET AL	
	Examiner	Art Unit	
	Padmavathi v Baskar	1645	

-- Th MAILING DATE of this communication appears on the cover she t with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 January 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1, 3, 5-16, 19, 21-23, 25-29 and 33 - 34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3, 5-16, 19, 21-23, 25-29 and 33 - 34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ ~~Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.~~

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☒ Interview Summary (PTO-413) Paper No(s). *15* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Response to Amendment

1. The amendment filed on 1/21/03 has been entered into the record.

Upon further consideration, the final rejection as set forth in the previous office action is hereby withdrawn. Claims 20, 31 and 32 have been canceled. Claims 1, 22, 25, 26 and 27 have been amended. New claims 33-34 have been added. Claims 1, 3, 5-16, 19, 21, 22, 23, 25-29, 33 and 34 are pending in the application.

2. In view of amendment to the claims 1 and 22, the rejection under 35U.S.C. 112, second paragraph is withdrawn.

3. In view of amendment to the claim 1, the rejection under 35 U.S.C. 102(b) as being anticipated by Ligler et al 1996, U.S.Patent 5,496,700 is withdrawn.

4. In view of amendment to the claims 1 and 22, the rejection under 35 U.S.C. 103(a) as being unpatentable over Ligler et al 1996, U.S.Patent 5,496,700 and in view of Litman et al 1983, U.S.Patent 4,391,904 is withdrawn.

5. In view of amendment to the claims 1, the rejection under 35 U.S.C. 102(b) as being anticipated by Mesnage et al 1997 (Molecular Microbiology 23 (6), 1147-1155) is withdrawn.

Claim objection

6. Claims 21, 25, 26 and 27are objected to because of the following informalities: Appropriate correction is required.

Claim 21 depends from canceled claim 20.

Claims 25, 26 and 27 depend from a subsequent claim.

Claim Rejections - 35 USC § 112, second paragraph

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

8. Claims 1, 3, 5-16, 19, 21, 22-23, 25-29 and 33-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 22 are rejected as being vague and indefinite for the recitation of "other Bacillus"

Does claim 1 indicate that the complex does not bind to other SAP from other species as well as other strains of B.anthracis?

Does claim 22 indicate that the antibodies do not bind to other Bacillus SAP from other species as well as other strains of B.anthracis?

Claim 3 is rejected as being vague for the recitation of "strain". Does applicant intend to mean B.anthracis in a test sample?

Claim 29 is rejected as being vague. It is not clear to which positive control that comprises a polypeptide that comprises an antigenic determinant of a B.anthracis SAP applicant is referring? Does applicant intend to mean the claim to read as The kit according to claim 22, wherein the kit further comprises a positive control comprising B.anthracis SAP as set forth in SEQ.ID.NO:1, wherein said SAP comprises antigenic determinant, wherein said antigenic determinant binds to the antibodies specific for B.anthracis?

Claim Rejections - 35 USC § 112, first paragraph

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 1, 3, 5-16, 19, 21, 22-23, 25-29 and 33-34 are rejected under 35 U.S.C. 112, first paragraph as containing subject mater which was not described in the specification in such a

way so as to enable one skilled in the art to which it pertains or with which it is most nearly connected to make and/or use the invention.

The claims are directed to a kit and a method of specifically detecting the Bacillus anthracis surface array protein (SAP) SEQ.ID.NO: 1 in a test sample, the method comprising: contacting a test sample with a first antibody that specifically binds to B.anthracis SAP as set forth in SEQ.ID.NO: 1, where in the first antibody forms a complex with the SAP but does not form a complex with other protein from other Bacillus present in a sample and detecting the complex with a labeled second antibody that binds to the complex, wherein the detection of the complex is indicative of the presence of B.anthracis. The claims are further drawn to the first or second antibody being recombinantly produced, polyclonal or monoclonal. Additionally, the claims are drawn to a method wherein the test sample is not cultured prior to contacting with the first antibody and the first and second antibodies bind different epitopes.

The instant claims are evaluated for enablement based on the Wands analysis. Many of the factors regarding undue experimentation have been summarized in In re Wands, 858 F.2d 731,8 USPQ2d 1400 (Fed.Circ.1988) as follows:

(1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The nature of the disclosed invention concerns a method of detecting surface array protein in environmental samples without prior culturing environmental samples. The state of the prior art indicates (See page 614 of Toumelin et al 1995, Journal of Bacteriology, 177: 614-620) that virulent bacilli are encapsulated and when the capsule is absent, the cell wall appears to be layered and is known as S-layer and is composed of surface array protein (SAP).

The state of the art also suggests that antibody based detection of biological warfare (BW) agents suffers from drawback because of interference from other environmental contaminants and fails to meet the detection threshold levels (see column 1, lines 39-55 in U.S.Patent 6,448,016).

The specification discloses a "test sample" as a sample obtained from a non-laboratory source that is not known to contain B.anthracis (i.e., unknown sample other than lab source in page of the instant specification). The specification, however, provides no working examples demonstrating (i.e., guidance) enablement for the claimed method and a kit because the specification lacks guidance in disclosing a test sample obtained from a non- laboratory source used in this method. The specification only teaches using the lab grown stern strain in the disclosed method. Further the specification lacks support for a method of specifically detecting the B.anthracis in test samples comprising biological warfare (BW) agents such as samples comprising spores and virulent bacteria. It is not clear whether or not all spores will express SAP (SEQ.ID.NO: 1) and the claimed method or kit would be able to detect SAP (SEQ.ID.NO:1) in any and all B. anthracis strains in a test sample. Further, the specification fails to indicate that the disclosed SAP (SEQ.ID.NO: 1) is present in all strains of B.anthracis including spores and virulent bacteria. The specification teaches a specific antibody that binds to SAP but fails to teach antibodies that bind to different epitopes. . Additionally it is unclear to which epitopes the two antibodies bind. Furthermore, the specification fails to demonstrate that the antibody based method of detection of a test sample (including biological warfare agents in environmental sample) would not interfere from other environmental " contaminants" that would undoubtedly be present in an environmental sample. Moreover, it appears from the specification that only samples with known surface array protein were tested and no samples containing spores (which would be indicative of that which would bee found in the environment). In view of the state of

the art, the amount of guidance provided by the specification (i.e., lack of working examples using "test samples" as defined by the specification) and the nature of invention, a method of specifically detecting the Bacillus anthracis surface array protein (SAP) SEQ.ID.NO: 1 in a test sample is not sufficient one skilled in the art to make and/or use the invention as claimed. Therefore, a method of specifically detecting the Bacillus anthracis surface array protein (SAP) SEQ.ID.NO: 1 in a test sample must be considered highly unpredictable, requiring a specific demonstration of efficacy on a case-by-case basis. Absent such demonstration, the invention would require undue experimentation to practice as claimed.

. Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 22, 25, 29, 33 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Phillips et al 1988(Journal of Applied Bacteriology 64: 47-55.

The claims are drawn to a kit comprising an antibody and a label. The claims are further drawn to first and second antibodies, wherein said antibodies are monoclonal or polyclonal antibodies and first antibody immobilized on a solid support.

Phillips et al disclose antibody preparations conjugated to fluorescein labels and are immobilized on a glass slide (solid support) with preparations of spores from B.anthracis (page 49). The antibodies were prepared against spores from B.anthracis strains (page 49). The antibodies were used in immunofluorescence assays. The antibodies and label of Phillips et al

appear to be the same as the claimed kit comprising antibodies and label. Characteristics such as specific binding to surface array protein (SEQ.ID.NO: 1) would be inherent in the antibodies of Phillips et al. Limitations such as recombinant, detecting the presence or absence of B.anthracis are being viewed as process and intended use limitations respectively.
Since the Office does not have the facilities for examining and comparing applicant's kit comprising antibodies and label with the product, antibody preparations conjugated to fluorescein labels of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product, kit comprising antibodies and label and the product of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

13. Claims 22, 23, 26, 27, 33 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Phillips et al 1988(FEMS Microbiology 47: 169-178).
The claims are drawn to a kit comprising an antibody and a label. The claims are further drawn to first and second antibodies, wherein said antibodies are monoclonal or polyclonal antibodies and first antibody immobilized on a solid support.

Phillips et al disclose monoclonal antibodies and a fluorescein conjugated anti-mouse labels and are immobilized on a glass slide (solid support) with preparations of spores from B.anthracis (page 172). The antibodies were prepared against B.anthracis spore antigens (page 171). The antibodies were used in immunofluorescence assays. The antibodies and label of Phillips et al appear to be the same as the claimed kit comprising antibodies and label. Characteristics such as specific binding to surface array protein (SEQ.ID.NO: 1) would be inherent in the antibodies of Phillips et al. Limitations such as recombinant, detecting the presence or absence of B.anthracis are being viewed as process and intended use limitations respectively.

Since the Office does not have the facilities for examining and comparing applicant's kit comprising antibodies and label with the product, antibody preparations conjugated to fluorescein labels of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product, kit comprising antibodies and label and the product of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Status of Claims

14. No claims are allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padma Baskar whose telephone number is (703) 308-8886. The examiner can normally be reached on Monday through Friday from 6:30 AM to 4 PM EST
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Padma Baskar Ph.D.

6/17/03

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600